

## **Additional Information for Results obtained from the MTD test used in the identification of *M. tuberculosis***

The following information may be used to assist in the interpretation of the results obtained by the MTD test.

If the MTD reports - *Mycobacterium tuberculosis* complex rRNA detected, the following information may be considered.

Specimen may contain both MOTT and *M. tuberculosis* or *M. tuberculosis* alone.

If the first sputum specimen is smear-positive and NAA-positive, the patient can be presumed to have TB without additional NAA testing.

If sputum is smear-negative and MTD positive, additional specimens (not to exceed three) should be tested with MTD. The patient can be presumed to have TB if a subsequent specimen is MTD-positive.

If the MTD test reports - No *Mycobacterium tuberculosis* complex rRNA detected, the following information may be considered.

Specimen may not contain *M. tuberculosis*, the result may be falsely negative due to low numbers of *M. tuberculosis* in the presence or absence of MOTT, or the result may be falsely negative due to assay interference by specimen inhibitors. Testing of another patient specimen is recommended if active tuberculosis is clinically suspected or specimen inhibition is suspected. The clinician must rely on clinical judgment in decisions regarding the need for antituberculous therapy and further diagnostic work-up, because negative NAA results do not exclude the possibility of active pulmonary TB.

If the first sputum is smear positive and NAA negative, a test for inhibitors should be done.

If inhibitors are not detected, additional specimens (not to exceed a total of three) should be tested.

The patient can be presumed to have NTM if a second sputum specimen is smear positive, NAA negative and has no inhibitors detected.

If inhibitors are detected, the NAA test is of no diagnostic help. Additional specimens (not to exceed a total of three) can be tested with NAA.

If sputum is smear negative and MTD negative, an additional specimen should be tested with MTD. The patient can be presumed not to be infectious if all smear and MTD results are negative.

All information was obtained from the package insert for MTD test provided by GenProbe.